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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 5:20-cv-0565-LCB**
	)	
ALEX AZAR,	)	**OPPOSED**
	)	
Defendant.	)	
	)	
	)	

EDWIN BANK'S BRIEF RE: STANDING

Pursuant to this Court's Order of September 20, 2021, Mr. Banks submits the following brief concerning the issue of standing. Mr. Banks has standing on three bases: 1) Mr. Banks has suffered an economic injury in the form of paying Medicare premiums and not receiving the promised benefits to which he is "entitled"; 2) Mr. Banks has suffered an injury from the denial of his statutory rights to Medicare payment of his claims; and 3) Mr. Banks has suffered a present injury and/or suffers a substantial risk of future injury as a result of being charged with the knowledge of the denial in this case and the loss of entitlement to the Medicare "mulligan" payment and risk of being held personally liable for future claims for TTFT coverage.

Under any or all of these bases, Mr. Banks has standing.

I. BACKGROUND

A. Medicare Eligibility

In order to even be eligible for Medicare, a person (or their spouse) must have paid Medicare taxes for 10 years and otherwise qualify (*e.g.*, be 65 or older). *See* 42 U.S.C. §§ 402, 414, and 1395c. Then, if the person elects, they can pay additional money (*i.e.*, premiums) to be covered by Medicare Part B. Medicare Part B is a voluntary insurance program financed by premiums that covers various non-hospital expenses, including durable medical equipment. *See* 42 U.S.C. §§ 1395j and 1395k.

As required by the statutes, the Secretary determines the amount of the premiums based on individual characteristics (*e.g.*, the person's adjusted gross income (AGI)), ways in which the premiums can be paid, and is required to terminate coverage for non-payment of the premiums. *See* 42 U.S.C. §§ 1395r (determining the amount of premiums); 1395s (payment of premiums); and 1395q(b)(2) (coverage terminated for non-payment of premiums).

In exchange for payment of the premiums, beneficiaries are "entitled" to have Medicare pay for qualifying services/devices. *See* 42 U.S.C. §§ 1395ff(a)(1)(A) and 1395k(a)(1)/(a)(2).[1]

[1] Absent payment of qualifying claims, there would be no point in beneficiaries paying premiums and they could keep their money.

Currently, the premiums for Medicare Part B range from $148.50 to $504.90 per month and there is no dispute that Mr. Banks paid the Medicare premiums for the period relevant to this case.

B. Medicare Payment Statutes and Regulations

In the interests of brevity, Mr. Banks will not repeat the treatment of the Medicare "mulligan" provisions of 42 U.S.C. § 1395pp(a) discussed in Banks' co-pending motion to take discovery. *See* Doc. 66. In sum, as stated there, a denial that is not reversed charges the beneficiary with "knowledge" of the denial, precludes recovery under § 1395pp, and potentially subjects the beneficiary to personal liability – as demonstrated in the *Holt* decision, attached hereto as Exhibit A.

II. DISCUSSION

As described by the Supreme Court in *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992), a plaintiff must satisfy three requirements to meet Article III's requirements for standing. First, a plaintiff must have suffered an injury in fact, *i.e.*, an invasion of a legally protected interest, which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of. Third, it must be likely that the injury will be redressed by a favorable decision. *Id.* at 560.

A. Mr. Banks Has Suffered an Economic Injury and Has Been Harmed

That Mr. Banks has suffered an economic injury is readily apparent simply considering what was promised under the statutes, what he paid, and what actually happened. As detailed above, Medicare Part B is a "voluntary insurance program" financed in part "from premium payments by enrollees." *See* 42 U.S.C. § 1395j. In exchange for payment of the premiums, beneficiaries are "entitled" to have Medicare pay for qualifying services/devices. *See* 42 U.S.C. §§ 1395ff(a)(1)(A) and 1395k(a)(1)/(a)(2). In the present case, in addition to at least 10 years of taxes deducted specifically for Medicare and all the premium payments made in the months/years before he became ill, Mr. Banks paid between ~$450 and $1,500 for coverage for the three months specifically at issue.

Assuming the allegations of the Complaint to be true (as the Court must at this stage), the Secretary failed to honor the promises of the statutes and improperly denied payment for qualifying items/services to which Mr. Banks was entitled. Thus, Mr. Banks is out of pocket at least the ~$450-$1,500 Mr. Banks paid for something he did not receive (*i.e.*, Medicare coverage of qualifying claims). Having been denied the benefit of the Medicare Part B bargain for which he paid, in effect, this is a suit by Mr. Banks for performance. Thought about differently, if Mr. Banks simply kept the premium payments for the months at issue, he would have $450-

$1,500 more in his pocket and received exactly the same thing from the Secretary – nothing.[2]

Accordingly, the economic harm to Mr. Banks is apparent. *See, e.g.*, *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190, 2204 (2021) ("As *Spokeo* explained, certain harms readily qualify as concrete injuries under Article III, the most obvious are traditional tangible harms, such as physical harms and monetary harms. If a defendant has caused physical or monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III.").

Thus, simply applying *Lujan*, Mr. Banks has standing. First, he has suffered an injury in fact (*i.e.*, the loss of $450-$1,500 and/or invasion of his legal right to Medicare Part B coverage secured by paying the premiums), that invasion is "concrete and particularized", and the injury actually already occurred. Second, there is a causal connection between the injury and the conduct complained of. Third, the injury can be redressed by a favorable decision (*i.e.*, an Order directing the Secretary to provide coverage of Mr. Banks' claims). Accordingly, Mr. Banks has standing.[3]

[2] Indeed, why voluntarily buy insurance if the insurance company (in this case Medicare Part B) is going refuse to honor promises and there is no recourse?

[3] That the Medicare Part B premiums are key to the "voluntary insurance" Medicare Part B program is demonstrated by the fact that, under the statute, failure to pay the premiums results in termination of coverage. *See* 42 U.S.C. § 1395q(b)(2) (coverage terminated for non-payment of premiums).

Having taken hundreds of dollars from a person suffering from brain cancer on the (so far) false promise of paying for qualifying items/services,[4] the Secretary contends that Mr. Banks is not injured thereby. This is so, the Secretary contends, because the harm to Mr. Banks is offset by the fact that Mr. Banks still got the treatment from Novocure *this time*.[5]

The Secretary's theory that payments (in the form of the treatment itself) from Novocure should be credited against the Secretary's liability (indeed, to offset it so completely that Mr. Banks lacks standing) flies in the face of the "collateral source rule." *See, e.g., Higgs v. Costa Crociere S.P.A. Co.*, 969 F.3d 1295, 1310 (11th Cir. 2020) (*citing* RESTATEMENT (SECOND) OF TORTS § 920A(2) ("Payments made to or benefits conferred on the injured party from other sources are not credited against the tortfeasor's liability, although they cover all or part of the harm for which the tortfeasor is liable.")).

[4] It is notable that throughout the entire claim process and litigation during which the Secretary has failed and refused to perform his side of the insurance bargain, the Secretary has never offered to return the premiums extracted from Mr. Banks on promises of coverage.

[5] Of course, the treatment for the three months at issue was provided to Mr. Banks without requiring payment up-front (*i.e.*, on credit). Thus, by providing treatment without requiring payment up-front or proof that Mr. Banks had the resources to pay, Novocure advanced Mr. Banks credit of more than $60,000. If the denial in this case is not reversed, no rational economic actor would repeat that experience a second time. Accordingly, absent reversal of this case, Mr. Banks could be required to sign an ABN as a condition of providing treatment – that is, assuming that Mr. Banks had the personal resources to cover treatments costing more than $20,000/month.

The "collateral source rule" is a feature of the federal common law. *See, e.g.*, *Gill v. Maciejewski*, 546 F.3d 557, 564-65 (8th Cir. 2008); *Perry v. Larson*, 794 F. 2d 279, 286 (7th Cir. 1986); *Friedland v. TIC-The Indus. Co.*, 566 F.3d 1203, 1205 (10th Cir. 2009); Rofail v. U.S., 2009 WL 1703236 at *13-15 (E.D. NY. June 18, 2009) (collateral source rule applies in Jones Act case and prevents offset of monies received from Social Security and Medicare). Simply applying that rule to this case, the Secretary should not be heard to contend that Mr. Banks was not injured (i.e., the Secretary's liability was offset to zero) because Mr. Banks received treatment from Novocure, even though the Secretary refused/refuses to honor the Medicare Part B agreement.

Mr. Banks has suffered an actual harm in the form of an economic injury and has standing.

B. Mr. Banks Has Standing Based On The Denial Of His Substantive, Statutory Rights[6]

Even if Mr. Banks had not actually paid premiums and Medicare Part B was a straight government benefits program (rather than a form of insurance contract),

[6] Mr. Banks understands that, while not deciding the issue of standing, the Eleventh Circuit's remand decision made certain comments regarding standing based solely on the denial of a statutory right. Respectfully, Mr. Banks believes that a more detailed review of the issue as contemplated by the Eleventh Circuit would either resolve the matter in Mr. Banks' favor or properly present the issue for consideration by the Eleventh Circuit on appeal, if necessary.

Mr. Banks would have standing based on the denial of his substantive statutory rights.

As set forth above, pursuant to 42 U.S.C. §§ 1395ff(a)(1)(A) and 1395k(a)(1)/(2),[7] Congress has created a statutory benefit to have Medicare pay for Mr. Banks' treatments. Pursuant to 42 U.S.C. §§ 405(g) and 1395ff, Mr. Banks has brought suit to challenge the denial of this benefit.

The most recent case from the Supreme Court addressing standing is *Transunion*. There, *citing Spokeo, Inc. v. Robbins*, 578 U.S. 330, 340 (2016), the Supreme Court instructed courts to:

> assess whether the alleged injury to the plaintiff has a "close relationship" to a harm "traditionally" recognized as providing a basis for a lawsuit in American courts. That inquiry asks whether plaintiffs have identified a close historical or common-law analogue for their asserted injury.

141 S.Ct. at 2204. *TransUnion* approvingly cites an article from Justice Scalia in its standing analysis which is highly relevant here. *Id.* at *6 (*citing Antonin Scalia*, THE DOCTRINE OF STANDING AS AN ESSENTIAL ELEMENT OF THE SEPARATION OF POWERS, 17 Suffolk U. L. Rev. 881, 885-6 (1983)). Justice Scalia stated there:

> As I would prefer to view the matter, the Court must always hear the case of a litigant who asserts the violation of a legal right. In some cases, the existence of such a right is, on the basis of our common-law traditions, entirely clear – as is the case, for example, when a statutory

[7] 42 U.S.C. § 1395ff(a)(1)(A) ("whether an individual is entitled to benefits"); 42 U.S.C. §1395k(a)(1) ("entitlement to have payment made to him or on his behalf") / (a)(2) ("entitlement to have payment made on his behalf")

> provision requires an agent of the executive to provide a particular benefit directly to a particular individual.

Id. at 885-86. Applying this analysis here, because the denial of a particular benefit (Medicare payment for treatments) to a particular individual (Mr. Banks) is an "entirely clear" basis for standing based on our common law traditions, Banks has been injured and has standing. Indeed, this analysis tracks the Supreme Court's statements regarding standing in Medicare cases. *See also, e.g., Heckler v. Ringer*, 466 U.S. 602, 620 (1984) ("the Medicare Act provides both the substance and the standing for [the plaintiff's] claim").[8]

While in this case, the Secretary contends that Mr. Banks was not liable for the cost of his own treatment (which amounted to approximately $60,000), Banks has still suffered an injury because he has not received his statutory benefit of having Medicare pay for the treatment. Receiving medical care is of paramount importance (especially with regard to TTFT), but also important is who pays for that care. If care depends on the resources of patients themselves, their families, charities, or third-

[8] The analysis of *TransUnion* and *Spokeo* in this regard is a variant on the notion, discussed below, that Congress may create a statutory right or entitlement, the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially-cognizable injury in the absence of the statute. *See Warth v. Seldin*, 422 U.S. 490, 514 (1975). That is, with respect to certain statutes, the alleged violation of a substantive, statutorily-created right is, alone, a sufficient injury in fact to give rise to Article III standing. *See Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n. 3 (1973) ("Congress may enact statutes creating legal rights, the invasion of which creates standing, even though no injury would exist without the statute."); E. Chemerinsky, FEDERAL JURISDICTION (7th ed. 2016) § 2.3.2 at 73 ("Violations of rights created by statute are also sufficient for standing purposes."). Thus, in these circumstances, economic injury is not the touchstone of standing. Rather, it is the denial of a substantive statutory right.

parties with no duty to them, then medical care might not be available, might be foregone to avoid depleting frequently meager resources, or will only be available as long as those resources remain.

Having seen the effects of that approach (particularly on the aged/disabled population), in the Medicare Act of 1965, Congress chose that the cost of care for the aged/disabled should be paid through taxes deducted during the beneficiary's working years and deposited in the Medicare Trust Fund.[9] Thus, pursuant to 42 U.S.C. §§ 1395ff(a)(1)(A) and 1395k(a)(1)/(2), Congress expressly created a statutory benefit "entitling" beneficiaries to have Medicare pay for their claims, rather than foist that burden on another party. Because Mr. Banks has been denied his statutory benefit, he has been injured and, without more, has standing.

With regard to the second prong of the *Lujan* analysis (*i.e.*, causation), the alleged injury in this case (failure of Medicare to pay Mr. Banks' claims) was caused by the Secretary when he denied the claims at issue. With regard to the third prong of the *Lujan* analysis (*i.e.*, redressability), Mr. Banks' injury of being denied his statutory benefit can be redressed by an order directing the Secretary to cover the claims at issue.

[9] Along with additional financial contributions from the beneficiaries in the form of a 20% co-pay for covered claims as well as premiums.

Respectfully, rather than no "injury", what the Secretary really contends is that the injury has been offset (as discussed above). This is simply a variant on the long-discredited notion that an injury can be offset and thereby rendered non-actionable. *See, e.g., Ross v. Bank of America, N.A. (USA),* 524 F.3d 217, 222 (2d Cir. 2008) ("[T]he fact that an injury may be outweighed by other benefits, while often sufficient to defeat a claim for damages, does not negate standing.").

Presumably, no one would accept the premise that Social Security recipients are not injured if their statutory benefits were denied arbitrarily and capriciously, as long as the lost amount of social security revenue was offset by donations made by a local charity, family members, or others in response. The injury to the beneficiaries in that case is the denial of their promised statutory benefit. Medicare claims, like Mr. Banks', arise under the same statute as Social Security claims (42 U.S.C. § 405(g)) and Mr. Banks is injured in the same way when Medicare does not provide the promised benefit. Mr. Banks access to life-extending treatment should not and does not, depend on the "kindness of strangers." The Medicare Act and its creation of a statutory benefit to have Medicare pay for care exists to avoid that outcome.

Mr. Banks has standing because he has been denied his substantive statutory benefit of having Medicare pay for his treatments. Mr. Banks has suffered an injury that can be redressed by this Court and has standing.

C. Mr. Banks Has Standing Based On The Medicare "Mulligan"

Mr. Banks has standing based on the present loss of his right to the Medicare "mulligan" and/or substantial risk of future financial liability.

As discussed above, once a claim is denied, the Medicare beneficiary is charged with knowledge of that denial and that will be taken into account when the beneficiary submits additional claims. If a subsequent claim is denied, pursuant to 42 U.S.C. § 1395pp(a)(2)/(b)/(c), the question then becomes whether payment may be made under the "mulligan" provision. That is dependent on whether the beneficiary, the provider, or both knew/should have known that the claim would be denied.

With respect to the beneficiary, as stated in the Secretary's MEDICARE CLAIMS PROCESSING MANUAL, Chap 30, § 30, that "knowledge" may come from an ABN (putting the beneficiary on notice) *or* "May be established when the beneficiary receives notice of a recent claim denial for the same item or service." Indeed, § 30.1.1 of the same manual makes clear that knowledge that a claim will be denied does not even have to be in written form in order for the beneficiary to be charged with it and, therefore, ineligible for the "mulligan." *Id.* ("the beneficiary must be held liable under [§ 1395pp(a)(2)], even if no written notice was given by the appropriate source."

Accordingly, once a claim is denied, beneficiaries are charged with "knowledge" of the denial and are ineligible for the "mulligan." Further, pursuant to both the statute and the Secretary's own manuals interpreting it, if both the beneficiary and the supplier knew or should have known that the claim would be denied, no payment can be made on the claim and "the beneficiary will be held liable." 42 U.S.C. § 1395pp(c); MEDICARE CLAIMS PROCESSING MANUAL, Chap 30, § 30.1.1. As discussed, that is exactly what happened in *Holt* for another TTFT patient. Thus, unless the denial in this case is reversed, Mr. Banks will lose his right to the Medicare "mulligan" and that is an injury conferring standing.

At times, the Secretary has argued that "mulligan" is "only lost when the conditions of the new denial are 'comparable' to the earlier denial." Respectfully, that misreads the statute. Pursuant to § 1395pp(a)(2), if neither the provider nor beneficiary knew/should have known that a claim would be denied:

> payment shall, notwithstanding such determination, be made for such items or services[.] … *In each such case* the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services.

(emphasis added) (cleaned up). Thus, under the statute, *if a "mulligan" payment is made,* the Secretary must provide notice that payment will not be made again in comparable situations for the same item or service or comparable items or services in the future. This notice charges both the provider and the beneficiary with such knowledge.

However, as the Secretary's own manuals interpreting § 1395pp(a)(2) state, "knowledge" can come from any source and is not dependent on a prior "mulligan" payment. Thus, the simple denial of a claim charges the beneficiary with "knowledge" (regardless of differing reasons for denial) and the beneficiary loses the right to the "mulligan" and, again, the beneficiary has standing. Indeed, multiple courts have so found. *See, e.g., Townsend v. Cochran*, 2021 WL 1165142 (S.D.N.Y. March 25, 2021) (TTFT case); *Ryan v. Burwell*, No. 5:14-CV-00269, 2015 WL 4545806, at *5-7 (D. Vt. July 27, 2015).

Absent reversal, Mr. Banks will be charged with "knowledge" and that will dictate his eligibility for "mulligan" relief going forward.[10] *See, e.g., Jayne v. Herman*, 706 F.3d 994, 1000 (9th Cir. 2013) ("To the extent that the plan pre-determines the future, it represents a concrete injury that plaintiffs must, at some

[10] Counsel understands from Mr. Banks that, against the advice of his doctors, Mr. Banks has elected to take a break from using the TTFT device but intends to resume use if his condition changes.

point, have standing to challenge. That point is now, or it is never.") (internal citations and quotations omitted). This is a present harm which confers standing.

Moreover, as demonstrated by *Holt*, when both the provider and the beneficiary knew/should have known the claim would be denied, "the beneficiary will be held liable" even in the absence of an ABN. *See* MEDICARE CLAIMS PROCESSING MANUAL, Chap 30, § 30 ("note"). Indeed, the sheer existence of *Holt* belies the notion that beneficiaries cannot be held liable absent an ABN.

In other proceedings, the Secretary has pointed to 42 U.S.C. § 1395m(j)(4) as somehow "controlling" on beneficiary liability. By its own terms § 1395m(j)(4) only applies to "unassigned" claims while this case involves "assigned" claims. Thus, § 1395m(j)(4) is simply inapplicable.

Likewise, in other proceedings, the Secretary has contended that § 1395m(j)(4) incorporates § 1395m(a)(18)(A) and that that section is somehow relevant. Putting aside the basic inapplicability of § 1395m(j)(4), § 1395m(a)(18)(A) concerns refunds in cases of telephone solicitation and, again, is inapplicable.

Thus, beyond the present loss of his "mulligan" right, Mr. Banks faces a substantial risk of future harm in being held personally financially liable. *See Department of Commerce v. New York*, 139 S.Ct. 2551, 2565 (2019) (standing based on future injury "may suffice if … *there is a substantial risk that the harm will*

occur." (emphasis added) (citation omitted). Unless the denial in this case is reversed, all that has to happen for Mr. Banks to be subjected to ~$20,000/month in personal liability is for a claim to be denied and liability placed on him - just like the TTFT patient in Holt. Mr. Banks does not have to wait until that conflagration occurs before he has standing to have his claim heard. *Dimarzo v. Cahill*, 575 F.2d 15, 18 (1st Cir. 1978) (prisoners had standing to protest hazardous fire conditions - "One need not wait for the conflagration before concluding that a real and present threat exists."). *See also* 13A Wright, Miller, & Cooper, FEDERAL PRACTICE AND PROCEDURE § 3531.4 (Supp. 2018) (collecting cases).

Considered as either the present loss of their "mulligan" right or the substantial risk of financial liability, Mr. Banks has been injured and has standing.

III. CONCLUSION

At base, Mr. Banks paid $450-$1,500 for something he did not receive and to which he is entitled (*i.e.*, Medicare payment of his claims). No one should be heard to say that when a brain cancer patient makes these payments and is wrongly denied benefits, they are not injured and their claims should not be heard.

For the reasons set forth above, this Court should find that Mr. Banks has standing.

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CERTIFICATE OF SERVICE

I hereby certify that on October 12, 2021 I filed the foregoing with the Clerk of Court using the CM/ECF electronic filing system which will send notification of such filing to all counsel of record in this case.

/s/Robert R. Baugh
OF COUNSEL